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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,696	10/28/2005	Shuji Ozaki	14875-141US1 C1-A0220P-US	1270
26161 7590 01/07/2011 FISH & RICHARDSON P.C. (BO) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 01/07/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/530,696	Applicant(s) OZAKI ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 13-25, 28, 31-38 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 13-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-38, 42 and 43 is/are allowed.
- 6) ☒ Claim(s) 24, 25, 28, 31-34, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 31 and 35 have been amended.

Claims 7-12, 26, 27, 29, 30, and 39-41 have been cancelled.

Claims 1-6 and 13-23 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 16, 2006.

2. Claims 24, 25, 28, 31-38, and 42-45 are under examination.

3. The following office action contains NEW GROUNDS of Rejection.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 22, 2010 was filed after the mailing date of the non-final office action on April 23, 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

5. The proprietary information filed September 30, 2010 has been considered by the examiner.

Rejections Withdrawn

6. The rejection of claims 31, 35-38, and 42-44 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained/ NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 24, 25, 28, 31-34, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan, et al. (US PAT 5,747,654, issued May 5, 1998) in view of Matsuoka, et al. (Journal of Experimental Medicine, 1995. Vol. 181, pages 2007-2015, as cited on the IDS filed November 24, 2006), as evidenced by the specification.

The claims recite a method for producing an HLA-A antigen-recognizing minibody, the method comprising: (a) identifying a whole antibody that recognizes a domain selected from the group consisting of domain a1 and domain a2 of an HLA-A antigen; (b) producing a minibody version of the antibody of (a); and (c) assaying a cytotoxic activity of the minibody, wherein the minibody is an scFv or a diabody, further comprising: (d) determining whether the minibody has an increased cytotoxic activity compared to the antibody of (a), wherein the antibody of (a) is an IgG, wherein the scFv or the diabody comprises the same CDR amino acid sequences as the CDRs of the antibody of (a), wherein the minibody is a diabody comprising two scFv, wherein the cytotoxic activity is a cell death-inducing activity, wherein the cytotoxic activity is a cell growth-suppressing activity. An HLA-recognizing minibody produced by the method of claim 24.

Pastan, et al. teach a method of producing scFv and dsFv antibody fragments and measurement of the cytotoxicity of those antibody fragments (see III. Specific toxicity of B3(dsFv)-PE38KDEL towards B3-antigen expressing carcinoma cell lines and

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tables 6 and 7). Pastan, et al. do not teach an antibody that binds to HLA-A antigen, this deficiency is made up for in the teachings of Matsuoka, et al.

Matsuoka, et al. teach and RE2 monoclonal antibody and fragments of the antibody. Matsuoka, et al. teach measurement of cytotoxicity of the antibody (figure 1). The specification discloses that the RE2 antibody binds the $\alpha 2$ domain of mouse HLA class IA.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the HLA-A antibody of Matsuoka, et al. and produce an scFv minibody in view of Pastan, et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the HLA-A antibody of Matsuoka, et al. and produce an scFv minibody in view of Pastan, et al. because Pastan, et al. identify full length antibodies and produce scFv and dsFv antibody formats from those antibodies and measure the cytotoxicity of the scFv and dsFv antibodies. Note that the limitations of claims 24 and 25 do not require a specific increase or decrease of cytotoxicity, only the measurement of cytotoxicity. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the HLA-A antibody of Matsuoka, et al. and produce an scFv minibody in view of Pastan, et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

11. The provisional rejection of claims 44 and 45 under nonstatutory obviousness type double patenting as being unpatentable over claims 5 and 7 of copending application No. 11/547747 is maintained.

Applicant's arguments filed October 22, 2010 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that the '747 claims are later filed than the present application and presently remain under examination.

Response to Arguments

In response to this argument, the instant double patenting rejection is a provisional rejection because at this time neither set of claims have been determined to be allowable. Should the '747 claims have a notice of allowability or issue a patent, then the rejection would mature into a double patenting rejection. Should the instant double patenting rejection become the only remaining issue regarding the instant claims, then the rejection will be withdrawn and a notice of allowability would be issued in the instant case. Since neither set of claims have been deemed to be allowable at this time, the rejection is maintained.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

12. Claims 24, 25, 28, 31-34, 44 and 45 are rejected.

Claims 35-38, 42, and 43 appear to be in condition for allowance.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
December 28, 2010

/Anne M. Gussow/
Primary Examiner, Art Unit 1643